

Proposed Addition to Division of Medical Assistance N.C. Prior Authorization Program Sedative Hypnotics

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Therapeutic Class Code: H2E, H8B

Therapeutic Class Description: Sedative Hypnotics—Non-Barbiturate, Hypnotics, Melatonin MT1/MT2 Receptor Agonists

Medication	Generic Code Number(s)
Ambien, Ambien CR, Zolpidem	00870, 00871, 25456, 25457
Sonata, Zaleplon	92713, 92723
Prosom, Estazolam	19181, 19182
Dalmane, Flurazepam	14250, 14251
Halcion, Triazolam	14280, 14282
Doral	40870, 40871
Restoril, Temazepam	13840, 13841, 13845, 24036
Lunesta	23925, 23926, 23927
Rozerem	25202

Early and Periodic Screening, Diagnostic and Treatment Provision

Early Periodic Screening, Diagnostic and Treatment (EPSDT) allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary health care services to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service product or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be access at <http://www.ncdhhs.gov/dma/EPSDTprovider.htm>.

Criteria for Exceeding Quantity Limit of 15 units **per Calendar Month**

1. Patient must have a diagnosis of chronic primary insomnia lasting one month or longer. Patient must have received information on good sleep hygiene. Length of therapy may be approved for up to six months at a time.

OR

2. Patient must have a diagnosis of chronic secondary or co-morbid insomnia lasting one month or longer and has been evaluated for and is being actively treated for one of the following conditions:
 - a. an underlying psychiatric illness associated with insomnia
 - b. an underlying medical illness associated with insomnia (for example, chronic pain associated with cancer, inflammatory arthritis)

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- c. a sleep disorder such as restless legs syndrome, sleep-related breathing disorder, sleep-related movement disorder, or circadian rhythm disorder

Length of therapy may be approved for up to six months at a time.

OR

- 3. Patient is being discontinued from a sedative hypnotic and tapering is required to prevent symptoms of withdrawal. Length of therapy may be approved for up to three months at a time.

OR

- 4. Patient is being actively assessed for a diagnosis of chronic primary or secondary/co-morbid insomnia. Length of therapy may be approved for six months one time only. Additional information may be requested to substantiate this status.

Procedures

Changes in strength will not require additional prior authorization.

Prior authorization request forms will be accepted when submitted by mail or facsimile telecommunication methods only.

Recipients residing in skilled nursing facilities, intermediate care facilities, and intermediate care facilities for individuals with mental retardation are exempt from the prior authorization requirement for sedative hypnotics.

Glossary¹⁸

- 1. **Chronic Insomnia:** Insomnia may be defined as complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep. The disturbance may consist of one or more of three features: (1) difficulty in initiating sleep; (2) difficulty in maintaining sleep; or (3) waking up too early. A fourth characteristic, non-restorative or poor-quality sleep, has frequently been included in the definition, although there is controversy as to whether individuals with this complaint share similar pathophysiologic mechanisms with the others. Chronic insomnia has been defined by the recent NIH consensus panel as 30 days or more of the symptoms described above.
- 2. **Primary Chronic Insomnia:** "Primary insomnia" is the term used when no co-existing disorder has been identified.
- 3. **Secondary or Co-Morbid Insomnia:** Most cases of insomnia are co-morbid with other conditions. Historically, this has been termed "secondary insomnia." However, the limited understanding of mechanistic pathways in chronic insomnia precludes drawing firm conclusions about the nature of these associations or the direction of causality.
- 4. **Cognitive Behavioral Therapy:** ~~CBT refers to a number of varied nonpharmacologic treatments for insomnia and there is evidence that relaxation~~

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~~therapy and cognitive/behavioral therapy are effective in the management of chronic insomnia in subsets of the chronic insomnia population. A standardized “best practice” model has yet to be formulated and validated. However, sleep hygiene recommendations are one form of CBT for which patient education materials are readily available for use in primary care.~~

References

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8. Wyeth Pharmaceuticals. Sonata package insert. Philadelphia, PA: Dec. 2004.
9. *Insomnia: Assessment and Management in Primary Care*. NIH Publication No. 98-4088. Sept. 1998.
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11. *Drug Class Review on Newer Sedative-Hypnotics, Final Report*. Portland, OR: Oregon Evidence-based Practice Center, Oregon Health and Science University, Dec. 2005.
12. Buscemi N, Vandermeer B, Friesen C, Bialy L, Tubman M, Ospina M, Klassen TP, Witmans M. Manifestations and Management of Chronic Insomnia in Adults. Evidence Report/Technology Assessment No. 125. (Prepared by the University of Alberta Evidence-based Practice Center, under Contract No. C400000021.) AHRQ Publication No. 05-E021-2. Rockville, MD: Agency for Healthcare Research and Quality. June 2005.
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18. National Institutes of Health State of the Science Conference statement on Manifestations and Management of Chronic Insomnia in Adults, June 13-15, 2005. *Sleep.* 2005 Sep 1;28(9):1049-57.